#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/598,777 Confirmation No.: 1177

Applicant : Anja FECHER, et al.
Filed September 11, 2006

Title : TETRAHYDROPYRIDOINDOLE DERIVATIVES

TC/Art Unit : 1625

Examiner: : Rita J. DESAI Docket No. : 66535.000013

Customer No. : 21967

# MAIL STOP PATENT TERM EXT.

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

# REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)

Dear Sir:

Applicant requests reconsideration under 37 C.F.R. § 1.705(b) of the patent term adjustment of 591 days indicated for the above-identified application ("the '777 application"). The Determination of Patent Term Adjustment mailed December 16, 2009 indicated a patent term adjustment of 591 days based on a projected issue date of Tuesday, June 29, 2010 (the Tuesday before the date that is 28 weeks after the mailing date of the Determination). Applicant respectfully submits that the correct patent term adjustment based on an assumed issue date of June 29, 2010 is 884 days for the reasons set forth below.

The issue fee is being paid concurrently with this paper. Accordingly, this request is timely. See 37 C.F.R. § 1.705(b).

In accordance with 37 C.F.R. § 1.705(b)(1), please charge the fee set forth in 37 C.F.R. § 1.18(e) (\$200) to the undersigned's **Deposit Account No. 50-0206**. In the event any additional fees are required for consideration of this request, the USPTO is authorized to charge these fees to the undersigned's Deposit Account No. 50-0206.

### Remarks begin on page 2.

#### REMARKS

Applicant requests reconsideration under 37 C.F.R. § 1.705(b) of the patent term adjustment for the '777 application. As discussed below, the USPTO determination of Applicant delay of two (2) days and the calculation of Total PTA should be reconsidered. The patent term adjustment determination should reflect a patent term adjustment of 884 days based on the assumptions set forth in the Determination of Patent Term Adjustment mailed December 16, 2009.

#### Statement Under 37 C.F.R. § 1,705(b)(2)

The patent term adjustment ("PTA") under 35 U.S.C. § 154(b) listed on Determination of Patent Term Adjustment for the '777 application is 591 days. See Exhibit A (a copy of the Determination of Patent Term Adjustment). This determination is in error because (1) the USPTO considered the delay between Saturday, September 26, 2009 and Monday September 28, 2009 as Applicant Delay in contravention of 35 U.S.C. § 21 and 37 C.F.R. § 1.7(a), and (2) the USPTO failed to take certain action within the time frame specified in 37 C.F.R. § 1.702(a) and failed to issue a patent within three years of the actual filing date of the above-identified patent application in accordance with 37 C.F.R. § 1.702(b). See Wyeth v. Kappos, No. 2009-1120 (Fed. Cir. Jan. 7, 2010).

#### A. Wyeth v. Kappos

In Wyeth v. Kappos, the Federal Circuit considered the USPTO's interpretation of 35 U.S.C. § 154(b). This section provides three guarantees of patent term adjustment, two of which are at issue. The first is a one-day extension of patent term for every day that issuance is delayed due to the USPTO failure to comply with certain statutory deadlines such as fourteen months for a first office action. See 35 U.S.C. § 154(b)(1)(A)(i)-(iv); see also 37 C.F.R. § 1.702(a). These delays are called "A delays" or "A periods." The second adjustment is a one-day term extension for every day it takes the patent to issue after three years from the filing date. See 35 U.S.C. § 154(b)(1)(B); see also 37 C.F.R. § 1.702(b). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period."

Under the statute, if "A delays" and "B delays" overlap, "the period of adjustment granted ... shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A) The purpose of this section is to prevent double-counting of periods of delay. According to the USPTO's interpretation of this section, any "A delay" overlaps with any "B delay," and thus an applicant can only get credit for an "A delay" or a "B delay," whichever is larger, but never for both. Federal Circuit has rejected this interpretation. It concluded that periods of time "overlap" only if they occur on the same day. Therefore, if an "A delay" and a "B delay" occurs on a different day, then a patentee may obtain an extension of A + B days.

#### B. Calculation of PTA Under 37 C.F.R. § 1.703 Under Wyeth

The following facts are relevant for determining PTA for the '777 application:

- September 11, 2006 The '777 application is filed
- November 11, 2007 Fourteen months from the filing date have elapsed marking the beginning of "A delay."
- June 26, 2009 A Requirement for Restriction is mailed, ending the accrual of "A delay" after <u>593 days</u> of "A delay" have accumulated.
- May 18, 2009 Three years from filing date of application have elapsed marking the beginning of "B delay."
- September 26, 2009 The date that is three-months from the Restriction Requirement falls on Saturday, September 26, 2009.
- September 28, 2009 Applicant responds to the Restriction Requirement on the Monday following the September 26, 2009.
- December 8, 2009 An Interview Summary is mailed reflecting discussions regarding proposed examiner's amendment.
- December 8, 2009 A Supplemental Amendment is filed which adopts Examiner's suggestions discussed during the interview.
- December 16, 2009 A Notice of Allowance is mailed.
- June 29, 2010 The projected issue date in the Determination of Patent Term Adjustment based on 28-weeks from mailing of Notice of Allowance is June 29,

2010. The "B delay" based on assumptions set forth in the Determination of Patent Term Adjustment is 291 days.

#### 1. "A" Periods Under 37 C.F.R. § 1.702(a)

The USPTO failed to issue a first office action within 14-months of the filing date of this application. The restriction requirement in this case was first mailed on June 26, 2009, resulting in <u>593 days</u> of "A delay." See USPTO Patent Term Adjustment History, attached herewith as Exhibit B.

#### "B" Periods Under 37 C.F.R. § 1.702(b)

The number of days from the beginning of the "B period" (November 11, 2009, i.e., three years from the filing day of the application) to the end of the proposed "B period" (assuming the patent issues June 29, 2010, the Tuesday that is before 28-weeks from the Notice of Allowance as noted in the Determination of Patent Term Adjustment) is 291 days.

#### 3. Delay Attributed to Applicant

The USPTO has calculated Applicant's delay in this case as two (2) days. See Exhibit B, USPTO Patent Term Adjustment History. This determination is in error because the USPTO considered the delay between Saturday, September 26, 2009 and Monday September 28, 2009 as Applicant Delay in contravention of 35 U.S.C. § 21 and 37 C.F.R. § 1.7(a). As stated in 35 U.S.C. § 21, "[w]hen the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a Federal Holiday within the District of Columbia, the action may be taken, or fee paid, on the next succeeding secular or business day." Applicant cannot have been "deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application" by filing a response on the Monday following the "3-month period" when that period ends on a Saturday. Applicant therefore requests reconsideration of its determination of Applicant Delay set forth in the Determination of Patent Term Adjustment mailed December 16, 2009.

## 4. PTA = (A Period +B Period) - Applicant Delay

The PTA should be calculated as follows:

Patent Application No. 10/598,777 Attorney Docket: 66535.000013

A period = 593 days. See 1. above

B period = 291 days. See 2. above.

Applicant delay = 0 days. See 3 above.

(593 + 291) - 0 = 884 days

Accordingly, Applicant respectfully request that the '777 application be granted a minimum PTA of at least 884 days.

In view of the above remarks, it is respectfully requested that this Request for Reconsideration of Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a projected patent term adjustment of at least 884 days.

Bv:

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: March 16, 2010

Registration No. 31 196

Jeff B. Vockrodt Registration No. 54,833

HUNTON & WILLIAMS LLP Intellectual Property Department 1900 K Street, N.W., Suite 1200 Washington, D.C. 20006 (202) 955-1500 (telephone) (202) 778-2201 (fassimile)